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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,765

01/19/2005

Masahiro Ishikawa

2005-0023A

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WENDEROTH, LIND & PONACK, L.L.P.

2033 K STREET N. W.

SUITE 800

WASHINGTON, DC 20006-1021

EXAMINER

TSAY, MARSHA M

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

05/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/521,765	Applicant(s) ISHIKAWA ET AL.	
	Examiner Marsha M. Tsay	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) 11-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 10 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05/08/08</u> . | 6) <input type="checkbox"/> Other: ____. |

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The instant Office action is in response to Applicants' remarks received November 7, 2007. Claims 3-9 are canceled. Newly submitted claims 11-14 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims 11-14 are drawn to a different method than the originally examined invention, because it has different steps and endpoints. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 11-14 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-2, 10-14 are currently under examination.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Priority: The priority date is July 19, 2002.

Objections and Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bringe (WO 0019839; IDS 05/08/08).

Bringe discloses a method for preparing a dry β -conglycinin protein composition comprising a β -conglycinin content greater than 40%, the method comprising a heat treatment step, wherein the heat treatment step is selected from 80-90°C or 120-154°C, lowering the pH to precipitate protein, recovering a portion of the precipitated protein, adjusting the pH of the protein mixture to between pH 6.7-7.2, and then drying the β -conglycinin mixture (p. 65-66). In Example 8, Bringe discloses SPI (soy protein isolate) suspensions were prepared at 7% protein and adjusted to pH 5.6 using dilute HCl (p. 54 lines 1-6). The SPI suspension at pH 5.6 was heated to 90°C (p. 54, table 16) and then lowered to 20°C (p. 54 lines 12-13). The temperature range of 120-154°C, as noted above by Bringe, is an alternative temperature that can be used in the heat treatment step and is an acceptable sterilization temperature. Bringe does not explicitly teach an ionic strength of less than 0.2.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to recognize that the ionic strength disclosed by Bringe (3.5% NaCl) can be adjusted accordingly, to a pH strength of less than 0.2, during the heat treatment step (claims 1-2, 10). It would be reasonable for one of ordinary skill to recognize that the differences in the ionic strength of the heating step can be arrived at by the normal desire of scientists to improve upon

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what is already known and which provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages (MPEP 2144.05).

In their remarks, Applicants assert the Bringe reference fails to disclose or suggest the limitation of an ionic strength of less than 0.2, as set forth in amended claim 1. Applicants further assert that Bringe discloses 3.5% NaCl, which corresponds to an ionic strength of 0.58. Also, the Bringe reference does not disclose the effect of the present invention, i.e. reducing the hydration property and high viscosity of a solution of β -conglycinin protein, as set forth in new claims 11-14. Applicant's arguments have been fully considered but they are not persuasive.

Firstly, Applicants did not provide a reliable document and/or support of the position that 3.5% NaCl has an ionic strength of 0.58. Also, it is known that ionic strength is a function of pH. Therefore, 3.5% NaCl at different pH ranges would have different ionic strengths.

Further, as noted in MPEP 2144.05, “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, Bringe discloses a method of producing dry β -conglycinin protein which encompasses the elements as recited in claim 1, except for the ionic strength. However, as noted above, it would be reasonable for one of ordinary skill to recognize that the differences in the ionic strength of the heating step can be arrived at by the normal desire of scientists to improve upon what is already known and which provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages (MPEP 2144.05).

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Maryam Monshipouri/

Primary Examiner, Art Unit 1656

May 21, 2008